Indications

For use in adult and pediatric patients for the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated, including conditions such as syndromic craniosynostosis and midface retrusion.

The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.

Features

- Telescoping design utilizes internal distraction mechanism
- Multiple anterior footplate designs for a wide range of placement options on the zygoma and lateral orbital rim
- Posterior footplate allows variable positioning in the temporal region
- Optional activation arm extensions to fit patient’s anatomy
- System allows up to 40 mm of distraction
- Distractor bodies and footplates are made of Ti-6Al-7Nb
- For use with 1.5 mm titanium screws for bone fixation
- System designed for use with Synthes Titanium Contourable Mesh
Distractor Assembly

1  Assemble the distractor nut

Thread the distractor nut onto the distractor body.

2  Assemble the posterior footplate

Thread the posterior footplate onto the distractor body. The posterior footplate can be adjusted in 0.5 mm increments along the distractor body to best fit the patient's anatomy.

**Technique Tips:**
- Once the posterior footplate location is determined, finger-tighten the distractor nut against the posterior footplate for stabilization.
- A second posterior footplate can be threaded onto the distractor body to add stability to the device assembly.

3  Choose the anterior footplate

Choose the anterior footplate that best suits both the anatomy of the patient and the treatment plan.

Refer to pages 9 through 11 of this Technique Guide for optional footplate configurations.

**Anterior footplate features:**
- The plates with buttress can be used to push the bone segment forward, thus sharing the load of distraction with the screws.
- The footplates for mesh [487.988, 487.989] require reducing the lateral surface of the zygoma with a bur to allow the contourable mesh to sit flush against the bone. Screws must be placed in the holes closest to the footplate for adequate device stability.
- Symmetrical footplates [487.986, 487.987] permit the distractor to be angled for a downward distraction vector.
- Offset footplates [487.984, 487.985] permit the distractor to be placed on a vector parallel with the occlusion for a horizontal distraction vector. The buttress on these footplates should sit flush against the bone for adequate stability.
Distractor Assembly (continued)

4 Attach the anterior footplate

Engage the distractor body into the “slip-fit” of the anterior footplate. Insert the 1.2 mm machine screw to affix the anterior footplate to the distractor body.

Note: If the 1.2 mm machine screw is not used, the distractor body may be removed after consolidation, without a coronal incision. (This will leave the anterior footplates on the zygoma.)

Warning: If the 1.2 mm machine screw is not used, extra care should be taken to not reverse the distractor during distraction, as it can inadvertently disengage from the anterior footplate.

Optional: Attach activation arm extensions

If necessary, attach an activation arm extension to the distractor body to allow the activation hex to protrude through the soft tissue for remote activation. Choose the activation arm extension that best suits the patient and engage it with the distractor body by slipping it over the activation hex.* Secure the activation arm extension to the distractor body with a 1.2 mm machine screw. Be sure to fully tighten the screw.

Note: For younger patients, the distractor body length may be sufficient for percutaneous activation.

* See section for activation arm selections in the back of the technique guide.

5 Repeat steps 1–4 for the opposite side

Assembly shown is for patient’s left side.
Device Placement

The footplates can be contoured to the patient’s anatomy, on a 3-D anatomical model prior to surgery, or on the patient intraoperatively. If contouring the footplates intraoperatively, follow the surgical technique below.

1 Fit the distractor

Place a fully assembled distractor in the intended placement area to assess the bony anatomy and to determine the approximate anterior and posterior footplate location.

Reminder: Determine if the activation arm extension(s) are necessary for the activation hex to exit through the soft tissue for remote activation.

Technique Tip: It is recommended to place the distractor under the temporalis muscle when determining final placement.

2 Contour the footplates

Contour the anterior and posterior footplates using the Combination Bending Pliers. Undesired screw holes may be removed using the Mesh Cutter or the Plate and Rod Cutter. Each footplate should contain a minimum of four screws for adequate stability.

Technique Tips:

- Be sure to not overbend the footplates.

- The anterior footplates should span the zygomaticomaxillary sutures to ensure the maxilla advances with the rest of the midface.

- Placement of the footplates determines the advancement vector of distraction and should be aligned with advancement vectors determined by preoperative planning.
Mark the distractor location

Mark the distractor location prior to the down fracture by inserting two appropriate length screws through the anterior footplate and one appropriate length screw through the posterior footplate. Fully tighten the screws in the anterior footplate but do not tighten the screw in the posterior footplate.

**Technique Tip:** Placing screws in the posterior footplate may not be preferable at this time. Instead, mark the location of the footplate with a marking pen.

**Note:** Drilling a pilot hole is necessary when using self-tapping screws.

Repeat steps 1–3 on contralateral side

Remove the distractors

Remove the distractors by unscrewing the 1.2 mm machine screws and the posterior footplate screws. The anterior footplates can stay on the zygomas. This will help realign the devices after the down fracture.

**Technique Tip:** If desired, the anterior footplates can be removed with the distractor bodies prior to the down fracture.
6 Perform the down fracture

Perform the down fracture and ensure the midface segment is completely mobile.

*Important:* The midface must be completely mobile as the distractors are not intended to complete the osteotomy.

7 Reattach the distractors

Once the midface is completely mobilized, reattach the distractors by re-engaging the distractor bodies with the “slip-fit” of each anterior footplate. Insert the 1.2 mm machine screws to lock the anterior footplates and distractor bodies together. Reinsert the screws in the posterior footplates, at the previously marked locations. Insert appropriate length screws into the remaining screw holes. Fully tighten all screws.

*Reminders:*
- A minimum of four screws should be placed in each footplate for adequate stability.
- If necessary, activation arm extensions can be added to lengthen the distractors for remote activation.

*Technique Tip:* When using the 1.5 mm contourable mesh plate, the screw holes closest to the anterior footplate for mesh should contain bone screws. This will ensure stable fixation for distraction.
Confirm device stability and activation

Tighten the distractor nuts against the posterior footplates using the Combination Wrench. Using the Activation Screwdriver, turn each distractor in a counterclockwise direction, as marked on the screwdriver’s handle, to confirm the stability and verify the movement of the midface.

The midface should advance upon activation of the distractors. Before closure, return each distractor to its original position.

Warning: If the 1.2 mm machine screws were not used to lock the anterior footplates to the distractor bodies, ensure the two components are fully engaged when the devices are returned to their original position.
Postoperative Considerations

1 Suggested distraction protocol
Distraction should begin three to five days after device placement. To achieve lengthening, engage the activation hex with the activation screwdriver and rotate counterclockwise (in the direction of the arrow marked on the instrument). A rate of 1.0 mm of distraction per day is recommended to prevent premature consolidation. Each full rotation equals 0.5 mm of distraction.

Warning: The devices are capable of 40 mm of distraction (80 counterclockwise rotations). Distraction beyond this limit will cause the devices to separate.

2 Site care
- To avoid the accretion of dried blood to the device, a regimen of applying antibiotic ointment to the percutaneous port is recommended throughout the course of distraction.
- Upon the first activation, special care should be given to ensure that the activation hex is free from soft tissue adhesion. Similar care should be given on all subsequent activations to provide the best comfort for the patient.
- Keeping the hair short around the activation port can also be beneficial to the patient’s comfort during distraction.

3 Document progress
Distraction progress should be observed by documenting the movement of the infraorbital rim and anterior maxillary teeth. A Patient Care Guide is included with the Activation Screwdriver to help record and monitor distraction progress.
Consolidation

After the desired advancement has been achieved, the new bone must be given time to consolidate. The consolidation period should be at least six to eight weeks. This time period may vary in relation to the patient’s age. Adequate bone consolidation can be confirmed by manually verifying midface stability.

Device Removal

1. **If 1.2 mm machine screws were used:**
   
   If the 1.2 mm machine screws were used to lock the anterior footplates to the distractor bodies, it will be necessary to gain access to the screws in the anterior and posterior footplates for device removal.

2. **If 1.2 mm machine screws were not used:**
   
   If the 1.2 mm machine screws were not used, it is possible to remove the devices without gaining access to the anterior footplates. Using the Activation Instrument, turn each distractor clockwise at least 20 times to disengage the distractor bodies from the anterior footplates. Make an incision over each posterior footplate to gain access to the screws. Remove all screws in the posterior footplates and lightly pull the distractor bodies through the incisions, leaving the anterior footplates on the zygomas.
Anterior Footplate Options

Anterior foot, elevated,
right [487.984]
left [487.985]

Screw holes on these footplates are offset from the distractor body. This allows the distractor to be placed more in line with the vector of the occlusion, and to allow the placement of screws lower on the zygoma. The buttress acts as an aid to push the midface segment forward, sharing the load of distraction with the screws.

Note: The buttress on these footplates should sit flush against the bone for adequate stability.

Anterior foot, low profile,
symmetrical [487.986]

Screw holes on the footplate are symmetrical with the distractor body. This allows the distractor to be placed on an angle to achieve a downward vector of distraction. Engagement of the distractor body and the anterior footplate occurs on the medial side of the anterior footplate, making the distractor assembly a lower profile in the lateral orbital region.
Anterior Footplate Options (continued)

Anterior foot, elevated, symmetrical [487.987]
Screw holes on the footplate are symmetrical with the distractor body. This allows the distractor to be placed on an angle to achieve a downward vector of distraction.

Anterior foot, for mesh [487.988]
The footplate allows use of the 1.5 mm titanium contourable mesh plate.

Anterior foot, for mesh, with buttress [487.989]
The footplate allows use of the 1.5 mm titanium contourable mesh plate. The buttress acts as an aid to push the midface segment forward, sharing the load of distraction with the screws.
Attaching the contourable mesh to the anterior footplate:

1. Place the 1.5 mm titanium contourable mesh plate over the anterior footplate for mesh.

2. Align the three holes in the anterior footplate for mesh with the three screw holes on the edge of the 1.5 mm titanium contourable mesh plate.

3. Ensure the screw hole countersinks on the 1.5 mm titanium contourable mesh plate are facing upward.

4. Insert three 1.2 mm machine screws to affix the two plates together.

Note: Larger sizes of the 1.5 mm titanium contourable mesh plates are available if necessary for proper screw placement:
70 mm diameter [446.054]
100 mm diameter [446.055]
Activation Arm Extension Options

Titanium Rigid Extension, 20 mm length [487.992]

Titanium Universal Joint Extension,
20 mm length [487.993]

Flexible Cable Extension, 40 mm length [487.994]
L-605 Cobalt chromium alloy cable, with silicone tubing
The Midface Distractor Set [145.955]

**Implants**

487.980  Titanium Midface Distractor Nut, 7 mm hex, 8 ea.
487.990  Titanium Midface Distractor Posterior Foot, single vector, 4 ea.
487.982  Titanium Midface Distractor Assembly, 40 mm length, 4 ea.
487.992  Titanium Rigid Extension, 20 mm, 4 ea.
487.993  Titanium Universal Joint Extension, 20 mm, 4 ea.
487.994  Flexible Cable Extension, 40 mm, 4 ea.
487.995  1.2 mm Titanium Machine Screw, for Midface Distractor, 12 ea.

Titanium Midface Distractor Anterior Feet
487.984  Elevated, right, 2 ea.
487.985  Elevated, left, 2 ea.
487.986  Low profile, symmetrical, 4 ea.
487.987  Elevated, symmetrical, 4 ea.
487.988  For mesh, 4 ea.
487.989  For mesh, with buttress, 4 ea.
446.053  1.5 mm Titanium Contourable Mesh Plate, rigid, 30 mm diameter, 6 ea.

1.5 mm Titanium Cortex Screws, self-tapping, with StarDrive recess, 4 pkg. of 5
400.354  4 mm
400.356  6 mm
400.358  8 mm

1.5 mm Titanium Cortex Screws, self-drilling, with StarDrive recess, 4 pkg. of 5
400.754  4 mm
400.756  6 mm
400.758  8 mm

2.0 mm Titanium Emergency Screws, with StarDrive recess, 2 pkg. of 5
400.254  4 mm
400.256  6 mm
400.258  8 mm

**Instruments**

395.35  Combination Wrench, 7 mm width across flats, 2 ea.
314.402 Activation Screwdriver, 2 ea.
311.03  Handle, with mini quick coupling, small, 2 ea.
313.832 1.5 mm Screwdriver Blade, self-retaining, StarDrive, 2 ea.
347.964 Combination Bending Pliers, 2 ea.
391.952  Mesh Cutter
391.990  Plate and Rod Cutter

1.1 mm Drill Bits, Stryker J-latch, 2 ea.
317.14  4 mm stop
317.16  6 mm stop
317.18  8 mm stop

Screw Length Markers
304.104  4 mm, 1 pkg. of 10
304.106  6 mm, 1 pkg. of 10
304.108  8 mm, 1 pkg. of 10
304.104W For self-drilling screws, 4 mm, 1 ea.
304.106W For self-drilling screws, 6 mm, 1 ea.
304.108W For self-drilling screws, 8 mm, 1 ea.

**Cases and Lids**

304.686  Universal Instrument Tray
304.687  Universal Instrument Tray Lid
304.797  Titanium Midface Distractor Module Case

**Also Available**

446.054  1.5 mm Titanium Contourable Mesh Plate, rigid, 70 mm diameter
446.055  1.5 mm Titanium Contourable Mesh Plate, rigid, 100 mm diameter